

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P O Box 1450 Alexandra, Virguina 22313-1450 www.weylo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,260	02/23/2004	Warren Shapiro	14497.853	8880
86997 7590 0408/2010 Berenbaum Weinshienk PC 370 Seventeenth Street			EXAMINER	
			LILLING, HERBERT J	
Republic Plaza Denver, CO 80			ART UNIT	PAPER NUMBER
,			1657	
			NOTIFICATION DATE	DELIVERY MODE
			04/05/2010	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pscull@bw-legal.com kkalan@bw-legal.com intellectualproperty@bw-legal.com

#### UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte WARREN SHAPIRO and JON ANDERSON

Appeal 2009-013391 Application 10/785,260 Technology Center 1600

Decided: April 1, 2010

Before DONALD E. ADAMS, ERIC GRIMES, and JEFFREY N. FREDMAN, Administrative Patent Judges.

 ${\it FREDMAN}, {\it Administrative\ Patent\ Judge}.$ 

#### DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to compositions for protecting skin with Kaempferia galanga root extracts. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Appeal 2009-013391 Application 10/785,260

#### Statement of the Case

#### Background

"A number of botanically derived substances have been heretofore employed from time-to-time in a variety of body lotions" (Spec. 1, 1l. 16-17). According to the Specification, the prior art is "confined to use of methoxycinnamates as UV sunscreens or the use of mixtures of a number of botanicals to address removal of spots or freckles. None of the patents mention the inhibition of tyrosinase as the relief of chemical irritation" (Spec. 2, 1l. 24-26).

The Specification teaches a "lotion containing a small but effective amount of ethyl p-methoxycinnamate specifically obtained from Kaempferia Galanga Root Extract in a cosmetically and pharmacologically acceptable carrier. The preparation is found to prevent and treat chemically induced skin irritations" (Spec. 1, II. 8-11).

#### The Claims

Claims 11-15, 19-26, and 28-32 are on appeal. Claims 11 and 13 are representative. Separate arguments for the remaining claims were not presented. Therefore, claims 12, 14, 15, 19-26, and 28-32 stand or fall with claims 11 and 13. 37 C.F.R. § 41.37(c)(1)(vii).

#### Claims 11 and 13 read as follows:

11. A composition for protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation consisting essentially of an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga. 13. A composition according to claim 11 containing from about 0.2 up to about 1.0 weight percent of the root extract of Kaempferia Galanga.

### The prior art

The Examiner relies on the following prior art references to show unpatentability:

Voss et al.	US 5,972,315	Oct. 26, 1999
Matsuda et al.	JP 408157346	Jun. 18, 1996
Schade (Abstract)	DE 19849514 A1	May 4, 2000

#### The issues

- A. The Examiner rejected claims 11, 12, 14, 15, 19-22, 24-26, 28, and 30-32 under 35 U.S.C. § 102(b) as anticipated by Voss (Ans. 7)
- B. The Examiner rejected claims 11-15, 19-26, 28, and 30-32 under 35 U.S.C. § 102(b) as anticipated by Matsuda (Ans. 7-8)
- C. The Examiner rejected claims 11-13, 15, 19-21, 23, 25, and 31 under 35 U.S.C. § 102(b) as anticipated by Schade (Ans. 8-9).
- D. The Examiner rejected claims 13, 23, 28, and 29 under 35 U.S.C. § 103(a) as obvious over Voss (Ans. 10-11).
- E. The Examiner rejected claims 11-15, 19-26, and 28-32 under 35 U.S.C. § 103(a) as obvious over Matsuda (Ans. 11).
- F. The Examiner rejected claims 11-13, 15, 19-21, 23-25, 30, and 31 under 35 U.S.C. § 112, first paragraph, enablement and written description.

#### A. 35 U.S.C. § 102(b) over Voss

The Examiner finds that "Voss teaches in Example 1 b, a composition containing a concentration of ethyl p-methoxycinnamate which is 2% that is within the scope of claim 11" (Ans. 7).

Appellants argue that "Voss specifically does not include, teach or suggest the element claimed and taught by Applicant, which is protection against the harmful effects of tyrosinase or chemically induced irritation other than UV radiation" (App. Br. 10). Appellants argue that "Voss does not include, teach or suggest the 'other than UV limitation' of Applicants' claims and rather, teaches away from use of ethyl p-methoxycinnamate as anything but a UV B filter in a 2.0% concentration" (App. Br. 10). Appellants argue that "Appellants' composition of Kaempferia Galanga root extract is not taught or suggested by Voss whether for this or any other purpose" (App. Br. 11).

In view of these conflicting positions, we frame the anticipation issue before us as follows:

Does the evidence of record support the Examiner's finding that Voss inherently teaches a composition with "an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga" (Claim 11)?

# Findings of Fact (FF)

1. The Specification teaches that the "present invention is directed making and utilizing a therapeutic composition containing up to about 5.0 weight percent, preferably from about 0.1 to about 1.0 weight percent of

ethyl p-methoxycinnamate extracted from Kaempferia Galanga root" (Spec. 2, 1, 30 to 3, 1, 1).

- The Specification teaches that after extraction and purification, the "residue using conventional assay techniques, which need not be disclosed here, consists essentially of highly purified ethyl pmethoxycinnamate" (Spec. 3, Il. 18-23).
- The Specification does not define the transition phrase "consisting essentially of" (see, e.g., Spec. 3).
- Voss teaches a "cosmetic skin-care product for external use, which is based on UV-radiation-absorbing substances in combination with a free-radical scavenger system" (Voss, col. 1, II. 8-11).
- 5. Voss teaches a "[c]omposition as in Example 1a but additionally 2.0 g of ethyl p-methoxycinnamate as UV B filter" (Voss, col. 4, 1l. 47-48).
- The Examiner finds that in the Voss composition, there is "a concentration of ethyl p-methoxycinnamate which is 2%" (Ans. 7).

# Principles of Law

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

"It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." In re Cruciferous Sprout Litigation. 301 F.3d 1343, 1349

(Fed. Cir. 2002). See, e.g., MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999) ("Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.")

Once a prima facie case of anticipation has been established, the burden shifts to the Appellant to prove that the prior art product does not necessarily or inherently possess the characteristics of the claimed product. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) ("Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product."). *See also In re Spada*, 911 F.2d 705, 708-09 (Fed. Cir. 1990).

Analysis

Voss teaches a skin care composition (FF 4) which comprises a 2% concentration of ethyl p-methoxycinnamate (FF 5-6). Absent a clear indication in the Specification or claims of what the basic and novel characteristics of the claimed device actually are, the term "consisting essentially of" is construed as equivalent to "comprising." *PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Appellants argue that "Voss specifically does not include, teach or suggest the element claimed and taught by Applicant, which is protection against the harmful effects of tyrosinase or chemically induced irritation other than UV radiation" (App. Br. 10). Appellants argue that "Voss does not include, teach or suggest the 'other than UV limitation' of Applicants'

claims and rather, teaches away from use of ethyl p-methoxycinnamate as anything but a UV B filter in a 2.0% concentration" (App. Br. 10).

We are not persuaded. The claim limitation to "protecting mammalian skin from discoloration or harmful effects of tyrosinase or chemically induced irritation other than UV radiation" represents an intended use recitation for this composition claim (Claim 11). Appellants do not argue that Voss' composition differs from the composition claimed, only that Voss has a different intended use for the composition. It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable. *See In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

Appellants also argue that "Appellants' composition of Kaempferia Galanga root extract is not taught or suggested by Voss whether for this or any other purpose" (App. Br. 11). Appellants do not identify any structural difference between their claimed composition and the composition of Voss. As in *Schreiber*, the Examiner has shifted the burden to Appellants "to show that the prior art structure did not inherently possess the functionally defined limitations of his claimed apparatus". *Schreiber*, 128 F.3d at 1478. *Also see In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) ("Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.").

Appellants have provided no evidence that the composition of Voss would differ from the composition of claim 11.

#### Conclusion of Law

The evidence of record supports the Examiner's finding that Voss inherently teaches a composition with "an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga" (Claim 11).

#### B. 35 U.S.C. § 102(b) over Matsuda

The Examiner finds that Matsuda teaches "extracts of the claimed plant material within the scope of the claimed percentages" (Ans. 7).

Appellants argue that "Matsuda is a UV protectant. Appellants' invention is a non-UV protectant. These are not identical and thus Matsuda does not anticipate" (App. Br. 12). Appellants argue that "persons using the Matsuda product for treatment of sunburn would not inherently be treating a tyrosinase or chemical irritant or discoloration issue as provided here. There is thus no inherency from Matsuda" (App. Br. 12).

In view of these conflicting positions, we frame the anticipation issue before us as follows:

Does the evidence of record support the Examiner's finding that Matsuda inherently teaches a composition with "an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga" (Claim 11)? Findings of Fact

- 7. Matsuda teaches extraction of active fractions from Kaempferia galanga (see Matsuda trans. 6 ¶ 0016).
- 8. Matsuda teaches a cream with 0.3 % of Kaempferia galanga extract (see Matsuda Trans. 14-15  $\P$  0031).

## Analysis

Matsuda teaches a composition which has an effective amount of

#### 0.3 % of Kaempferia galanga root extract (FF 7-8).

Appellants argue that "Matsuda is a UV protectant. Appellants' invention is a non-UV protectant. These are not identical and thus Matsuda does not anticipate" (App. Br. 12). Appellants argue that "persons using the Matsuda product for treatment of sunburn would not inherently be treating a tyrosinase or chemical irritant or discoloration issue as provided here. There is thus no inherency from Matsuda" (App. Br. 12).

We are not persuaded. Appellants do not argue that Matsuda's composition differs from the composition claimed, only that Matsuda has a different intended use for the composition. As discussed above, it is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.

## Conclusion of Law

The evidence of record supports the Examiner's finding that Matsuda inherently teaches a composition with "an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga" (Claim 11).

## C. 35 U.S.C. § 102(b) over Schade

The Examiner finds that Schade "teaches isoamyl p-methoxycinnamate which . . . is one of the compounds that is known to be extracted from the 'root of Kaempferia Galanga'" (Ans. 8).

Appellants argue that "references neither [teach an] extract of Kaempferia Galanga nor a non-UV protectant. The reference cited by the examiner is isoamyl p-methoxycinnamate, also known as amiloxate" (App. Br. 13). Appellants argue that the "mere fact that the Schade reference teaches a UV protectant for a potential substituent of a Kaempferia Galanga

root extract does not teach or suggest the root extract itself nor that it would act as an 'other than UV' protectant" (App. Br. 13).

In view of these conflicting positions, we frame the anticipation issue before us as follows:

Does the evidence of record support the Examiner's finding that Schade inherently teaches a composition with "an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga" (Claim 11)? *Findings of Fact* 

- Schade teaches a composition that comprises "3-6 wt. %
  isoamyl p-methoxycinnamate" (Schade abstract).
- 10. The Examiner finds that "at least the following compounds were found to be extracted from the plant material from 'the root extract of Kaempferia Galanga': . . . isoamyl p-methoxycinnamate" (Ans. 4-5).

  Analysis

Schade teaches a composition which has an effective amount of 3-6 % of isoamyl p-methoxycinnamate (FF 9). It is undisputed that isoamyl p-methoxycinnamate is a compound found in the root extract of Kaempferia galanga (FF 10).

Appellants argue that the "mere fact that the Schade reference teaches a UV protectant for a potential substituent of a Kaempferia Galanga root extract does not teach or suggest the root extract itself nor that it would act as an 'other than UV' protectant" (App. Br. 13).

We are not persuaded. Appellants do not argue that isoamyl pmethoxycinnamate is not found in Kaempferia Galanga root extract, and therefore do not argue a difference in composition, but again argue that the prior art does not teach the intended use. As previously discussed, it is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.

Conclusion of Law

The evidence of record supports the Examiner's finding that Schade inherently teaches a composition with "an effective amount of up to about 5% by weight of a root extract of Kaempferia Galanga" (Claim 11).

D. and E. 35 U.S.C. § 103(a) over Voss or Matsuda

The Examiner finds that "Voss teaches in Example 1 b whereby the concentration of ethyl p- methoxycinnamate is 2% as well as disclosure also teaches that the percentage range is as low as 0.1 %" (Ans. 10-11). The Examiner finds that "Matsuda et al teaches several examples which includes [sic] extracts which extracts contain at least the ethyl p-methoxycinnamate in the extract as low as 0.1% that renders the claimed ranges prima facie obvious even if the extracts are slightly outside the actual ranges of the final concentration absent a showing of criticality for the claimed ranges" (Ans. 11).

Appellants argue that "Matsuda doesn't teach or suggest the limitations of the base claims 1 l, 21 or 26 including the 'root extract' (apparently not an extract by the same or similar process of Appellants' description) or the 'other than UV radiation' limitations" (App. Br. 15). Appellants argue that "claims 13, 23, 28 and 29 are believed to be allowable at least, because . . . they contain limitations not taught or suggested by Voss" (App. Br.14). Appellants also argue that "the Examiner provides no such evidence or affidavit supporting the Examiner's apparent taking of

Official Notice and the assertion that Appellants' development would have been obvious to one skilled in the art' (App. Br. 14).

In view of these conflicting positions, we frame the obviousness issue before us as follows:

Does the evidence of record support the Examiner's conclusion that Voss and Matsuda each renders obvious teaches a composition "containing from about 0.2 up to about 1.0 weight percent of the root extract of Kaempferia Galanga" (Claim 13)?

Findings of Fact

11. Voss claims a composition "wherein said one or more UV filter is present in an amount of 0.1 to 20%" (Voss, col. 6, 1l. 26-27).

Principles of Law

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Moreover, as our reviewing court stated in Peterson

In cases involving overlapping ranges, we and our predecessor court have consistently held that even a slight overlap in range establishes a *prima facie* case of

obviousness .... We have also held that a *prima facie* case of obviousness exists when the claimed range and the prior art range do not overlap but are close enough such that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 783 (Fed. Cir. 1985).

*In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). *Analysis* 

Matsuda teaches a composition which has an effective amount of 0.3 % of Kaempferia galanga root extract (FF 7-8).

Voss teaches a skin care composition (FF 4) which comprises a 2% concentration of ethyl p-methoxycinnamate (FF 5-6). Voss also teaches that the concentration of UV filter compounds such as ethyl p-methoxycinnamate may fall in a range between 0.1 to 20% (FF 11).

Appellants argue that "Matsuda doesn't teach or suggest the limitations of the base claims 11, 21 or 26 including the 'root extract' (apparently not an extract by the same or similar process of Appellants' description) or the 'other than UV radiation' limitations" (App. Br. 15). We are not persuaded for the reasons previously given, that the "other than UV radiation" limitation is an intended use recitation and that Appellants have the burden to demonstrate that the extract of Matsuda differs from that claimed.

Appellants argue that "claims 13, 23, 28 and 29 are believed to be allowable at least, because . . . they contain limitations not taught or suggested by Voss" (App. Br. 14).

We are not persuaded because Voss expressly suggests that UV filter compounds such as ethyl p-methoxycinnamate may fall in a range of 0.1 to 20% which overlaps that of the up to 1.0 weight percent of the root extract of Kaempferia Galanga of Claim 13 (FF 11). See In re Peterson, 315 F.3d at 1330. ("[T]he existence of overlapping or encompassing ranges shifts the burden to the applicant to show that his invention would not have been obvious.") Accordingly, we are not persuaded by Appellants' contention that the evidence fails to support the Examiner's conclusion (see App. Br. 14).

#### Conclusion of Law

The evidence of record supports the Examiner's conclusion that Voss and Matsuda each renders obvious teaches a composition "containing from about 0.2 up to about 1.0 weight percent of the root extract of Kaempferia Galanga" (Claim 13).

# F. 35 U.S.C. § 112, first paragraph, enablement and description

The Examiner finds that the "expression 'root extract of Kaempferia Galanga' does not define the 'composition' components since the term 'extract' is not a known compound but only a process step that depends upon the processing conditions" (Ans. 12). The Examiner finds that "the specification, while being enabling for the specific examples or claims not rejected, does not reasonably provide enablement for products defined by only the expression 'root extract' without defining the processing conditions or ingredients" (Ans. 13).

Appellants argue that "the scope and content of the root extract is defined by the extraction process and thus enabled and sufficiently described in the specification without need of more detail" (App. Br. 8).

Appeal 2009-013391 Application 10/785,260

In view of these conflicting positions, we frame the enablement and description issues before us as follows:

Does the evidence of record support the Examiner's conclusion that the Specification does not enable or describe a "root extract of Kaempferia Galanga" (Claims 11 & 13)?

Findings of Fact

# 12. The Specification teaches

the use of ethyl p-methoxycinnamate which has been extracted from Kaempferia Galanga root by placing the root in an alcohol bath, heating in the alcohol bath to extract the cinnamate from the root; separating the alcohol solution from the root residue, and thereafter heating the alcohol extract for a time sufficient to evaporate substantially all of the alcohol therefrom.

(Spec. 3, Il. 18-22).

## Principles of Law

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application.

In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). "[T]he question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation 'must not be unduly extensive." PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996).

It is the Examiner's "initial burden [to] present[] evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976). To satisfy the written description requirement, the inventor must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.*" *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

Analysis

The Examiner appears to be requesting a general decision regarding the use of the term "extract" (see Ans. 26). However, each case is decided on its own merits. *See In re Gyurik*, 596 F.2d 1012, 1018 (CCPA 1979).

On the facts of the claims before us, the Specification teaches and describes a particular root extract of Kaempferia galanga (FF 12). With regard to enablement, the Examiner has provided no evidence or reasoning which would demonstrate any unpredictability or undue experimentation in obtaining such a root extract.

The Examiner also concludes that the term "root extract" fails to satisfy the written description requirement. However, the Examiner has not provided any evidence or reasons to support this conclusion. In particular, the Examiner has not shown that the skilled artisan would not recognize a disclosure of a "root extract of Kaempferia galanga" in the Specification. The Examiner has not provided evidence or reasoning that the expressly disclosed species is not representative of Kaempferia galanga root extracts in general.

We therefore conclude that the Examiner has not satisfied the burden necessary to demonstrate that the claims fail to satisfy the requirements of 35 U.S.C. § 112, first paragraph.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that the Specification does not enable or describe a "root extract of Kaempferia Galanga".

#### SUMMARY

In summary, we affirm the rejection of claim 11 under 35 U.S.C. § 102(b) as anticipated by Voss. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 12, 14, 15, 19-22, 24-26, 28, and 30-32 as these claims were not argued separately.

We affirm the rejection of claim 11 under 35 U.S.C. § 102(b) as anticipated by Matsuda. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 12-15, 19-26, 28, and 30-32 as these claims were not argued separately.

We affirm the rejection of claim 11 under 35 U.S.C. § 102(b) as anticipated by Schade. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 12, 13, 15, 19-21, 23, 25, and 31 as these claims were not argued separately.

We affirm the rejection of claims 13, 23, 28, and 29 under 35 U.S.C. § 103(a) as obvious over Voss.

We affirm the rejection of claims 11-15, 19-26, and 28-32 under 35 U.S.C. § 103(a) as obvious over Matsuda.

Application 10/785,260

We reverse the rejection of claims 11-13, 15, 19-21, 23-25, 30, and 31 under 35 U.S.C. § 112, first paragraph, enablement and written description.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

# **AFFIRMED**

alw

BERENBAUM WEINSHIENK, PC 370 SEVENTEENTH STRET REPUBLIC PLAZA, SUITE 4800 DENVER, CO 80202